NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE INTEGRA LIFESCIENCES HOLDINGS CORPORATION SECURITIES LITIGATION	Civil Action No. 23-20321 (MAS) (TJB) **MEMORANDUM OPINION**

SHIPP, District Judge

This matter comes before the Court upon Defendants Carrie Anderson ("Anderson"), Peter Arduini ("Arduini"), Glenn Coleman ("Coleman"), Robert Davis ("Davis"), Jan De Witte ("De Witte"), Lea Knight ("Knight"), Steve Leonard ("Leonard"), and Jeffrey Mosebrook ("Mosebrook") (together, the "Individual Defendants") and Integra Lifesciences Holdings Corporation's ("Integra" or the "Company") (collectively, "Defendants") Motion to Dismiss (ECF No. 68) Lead Plaintiff Pembroke Pines Firefighters and Police Officers Pension Fund's ("Plaintiff" or "Lead Plaintiff") Consolidated Class Action Complaint ("CAC") (ECF No. 53). Plaintiff opposed (ECF No. 72), and Defendants replied (ECF No. 74). The Court has carefully considered the parties' submissions and reaches its decision without oral argument under Local Civil Rule 78.1(b). For the reasons below, Defendants' Motion to Dismiss is granted.

I. BACKGROUND[1]

This matter is a putative securities class action brought "on behalf of all persons or entities that purchased or otherwise acquired shares of Integra common stock between March 11, 2019

[1] For the purpose of considering the instant motion, the Court accepts all factual allegations in the Complaint as true. *See Phillips v. County of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008).

and July 28, 2024, inclusive (the "Class Period")." (CAC 1, ECF No. 53.) Lead Plaintiff is a pension plan that "administers retirement, disability, and death benefits for Pembroke Pines, Florida's police officers and firefighters." (*Id.* ¶ 23.) Defendant Integra was founded in 1989. (*Id.* ¶ 36.) The Company "is a medical device and technology company that develops and manufactures surgical instruments and regenerative tissue technologies." (*Id.*) Anderson served as Integra's Executive Vice President ("EVP") and Chief Financial Officer ("CFO") from June 24, 2019 to February 2, 2023. (*Id.* ¶ 27.) Arduini served as Integra's Chief Executive Officer ("CEO") and director from January 3, 2012 to December 1, 2021. (*Id.* ¶ 28.) Coleman served as Integra's Chief Operating Officer from June 24, 2022 to September 23, 2022. (*Id.* ¶ 29.) Davis was Integra's EVP and President of the Tissue Technologies division during the Class Period and was "responsible for the management of the division's regenerative tissue products." (*Id.* ¶ 30.) De Witte served as Integra's CEO and a director since December 2021, and Integra issued a press release announcing De Witte's "intent to retire" on February 28, 2024. (*Id.* ¶ 31.) Knight has served as Integra's EVP and CFO since June 2023. (*Id.* ¶ 32.) Leonard has served as Integra's Vice President ("VP") of Global Operations and Supply Chain since August 2020. (*Id.* ¶ 33.) Mosebrook has served as Integra's Senior VP of Finance and Principal Accounting Officer since January 2020. (*Id.* ¶ 34.)

A. Integra Acquires the Boston Facility

In 2015, Integra acquired TEI Biosciences, Inc. and TEI Medical Inc. ("TEI"), producers of biologic mesh products, which are mainly used for tissue reconstruction. (*Id.* ¶¶ 4, 37.) In this acquisition, Integra added the SurgiMend and Primatrix extracellular bovine matrix ("EBM") devices to its offerings. (*Id.* ¶¶ 37, 37 n.1.) Integra also assumed the lease of the only manufacturing center of the SurgiMend and Primatrix EBM devices in South Boston (the "Boston Facility"), described as "a converted, eighty-year[-]old school with a fragmented layout and

antiquated equipment and infrastructure." (*Id.* ¶ 38.) In a press release, Integra announced that those devices would create "a significant opportunity to build our platform and fuel a robust pipeline of regenerative products to accelerate Integra's overall growth" and expected gross margins of these products of "about 80%." (*Id.* ¶ 37.) Plaintiff alleges that Integra "increasingly promoted" SurgiMend and Primatrix brands as "key to the Company's top- and bottom-line growth." (*Id.* ¶ 39.)

B. cGMP Compliance

As a medical device manufacturer, Integra is subject to the United States Food and Drug Administration's ("FDA") regulations for medical drugs and devices, known as the Current Good Manufacturing Practice ("cGMP"). (*Id.* ¶ 41.) The CAC alleges that "Integra's business, reputation, and ability to manufacture and sell its medical devices depended on its strict compliance with cGMP." (*Id.*) Medical devices, such as SurgiMend and Primatrix EBM devices, are also subject to "adulteration provisions" of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") in 21 U.S.C. § 351. (*Id.* ¶ 42.) These provisions direct that a device is "adulterated, i.e., out of compliance with federal law" when "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable [cGMP] requirements." (*Id.* (quoting 21 C.F.R. § 351(h.)).)

The cGMP standards require Integra to "establish strong quality management systems and robust operating procedures, validate all testing procedures, control environmental conditions, prevent contamination, and detect and correct all quality deviations" to ensure that devices will be safe and effective. (*Id.* ¶ 44.) They also require Integra to develop a Corrective and Preventive Action ("CAPA") framework to identify and fix defects in manufacturing to ensure that they do not occur again. (*Id.* ¶ 45 (citing 21 C.F.R. § 820.100).) Since the FDA relies on companies' data

to ensure safe and effective medical devices and to make public health decisions, the cGMP also has "data integrity" requirements to ensure complete, accurate, and consistent data that is not manipulated or lost. (*Id.* ¶ 46.) It also "requires medical device manufacturers to validate each step in their manufacturing process, and to ensure they manufacture each of their products in the exact same validated manner." (*Id.* ¶ 43.) As part of these requirements, companies cannot "test into compliance," which is the practice of successively re-testing devices that have failed analytical testing and inspection until they pass, without investigating why the device failed or reporting the failed results. (*Id.* ¶ 47.)

To enforce the cGMP requirements, the FDA conducts periodic inspections of device manufacturing facilities. (*Id.* ¶ 48.) At the end of these inspections, the FDA meets with management to share its observations. (*Id.*) If the FDA finds any violations of the FD&C Act, it privately provides the manufacturer with a form called "Inspectional Observations," also known as an FDA Form 483 ("Form 483"). (*Id.* (citing 21 U.S.C. § 374(b)).) The Form 483 is issued to "the most responsible person available at the close of the inspection" and to "top management of the firm," but generally it is not published for or announced to the public. (*Id.* ¶¶ 49-50.) The FDA also provides the manufacturer with an Establishment Inspection Report ("EIR"), which gives additional details on the Form 483. (*Id*. ¶ 49.) If a manufacturer receives a Form 483, it has fifteen days to respond with "a root cause analysis, impact assessment, and a set of corrective and preventive actions." (*Id.* ¶ 50) If the FDA decides that a manufacturer did not take adequate corrective and preventive actions after being issued a Form 483, it may then issue a warning letter, which is published on its website shortly after being sent to the manufacturer. (*Id.* ¶ 51.) In addition to a warning letter, the FDA may also order the manufacturer to take remedial action, such as ceasing operations or recalling products. (*Id.* ¶ 52.)

C. FDA Inspections, Whistleblower Complaint, and Integra's cGMP Violations

1. 2018 Investigation

The FDA investigated the Boston Facility in the fall of 2018 and found cGMP violations that it detailed in a Form 483 that was privately issued to Integra on November 2, 2018 ("2018 Form 483") and discussed at a meeting with several Integra executives that same day. (*Id.* ¶¶ 54, 62.) The FDA also issued an EIR on November 28, 2018 ("2018 EIR") (together with the 2018 Form 483, the "2018 Inspection Reports"), which stated that Integra told the FDA to send all related correspondence directly to Arduini. (*Id.* ¶ 54.) Integra responded to the 2018 Form 483 and acknowledged the significance of the issues raised and stated that the Company would benefit from control improvements. (*Id.* ¶ 63.)

The cGMP violations in the 2018 Inspection Reports can be grouped into four different types of violations, each of which relate to "requirements for preventing toxic bacterial contamination of its surgical tissue reconstruction products." (*Id.* ¶¶ 54-61.) First, the FDA found that Integra was committing contamination control violations in seven different categories by, *inter alia*, failing to test its sterile surgical tissue regeneration products for endotoxins and failing to test water used in manufacturing for bacteria.[2] (*Id.* ¶ 55.) After reviewing thirty-five EBM surgical device lots from the Boston Facility, the FDA found that 43% of those devices initially failed endotoxin contamination testing, but they were "repeatedly retested" without justification until they passed inspection. (*Id.* ¶ 56.) Second, Integra was committing environmental control violations by failing to appropriately disinfect its "Clean Rooms"[3] and by failing to properly

[2] Bacterial endotoxins are "contaminants that, when present in medical devices implanted in the human body, can cause fever, sepsis, septic shock, and multi-organ failure." (CAC ¶ 5.)

[3] A "Clean Room" "is used in the medical device manufacturing industry to manufacture products in an aseptic (sterile) or controlled environment." (CAC ¶ 57 n.3.)

monitor and test whether these "Clean Rooms" were actually sterile. (*Id.* ¶ 57.) Third, Integra was committing process validation control violations in nine different categories by failing to re-validate processes critical to quality or that posed a high risk to EBM medical devices. (*Id.* ¶ 58.) Fourth, Integra was committing CAPA control violations by failing "to properly investigate and correct known product safety and quality failures." (*Id.* ¶¶ 59-60.)

2. 2019 Warning Letter

On March 6, 2019, five days before the start of the Class Period, the FDA issued a warning letter to Integra (the "2019 Warning Letter"), addressed to Arduini. (*Id.* ¶ 64.) The 2019 Warning Letter included the same observations as the 2018 Inspection Reports and warned Integra that it was not taking adequate remedial measures to fix those violations, and deemed devices manufactured in the Boston Facility "adulterated." (*Id.* ¶¶ 64, 66.) The FDA warned that failure to take proper action could result in regulatory action. (*Id.* ¶ 66.) Integra disclosed the 2019 Warning Letter to investors on March 11, 2019, and the FDA published the letter on its website about a week later, on March 19, 2019. (*Id.* ¶¶ 64, 67.)

On the same day that Integra disclosed the 2019 Warning Letter, it filed a Form 8-K with the Securities and Exchange Commission ("SEC") stating that "since the conclusion of the [FDA] inspection, [Integra] has undertaken significant efforts to remediate the observations and continues to do so," (*id.* ¶¶ 70, 267 (emphasis omitted)), and the letter "does not restrict the Company's ability to manufacture or ship products or require the recall of any products" (*id.* ¶¶ 70, 295).

Integra also addressed the 2019 Warning Letter more generally on its subsequent earnings calls. (*See id.* ¶¶ 299, 303.) On February 19, 2020, during its Q4 2019 earnings call, Coleman assured investors that Integra had undertaken "quality remediation efforts throughout 2019" and that "there are no patient safety issues" at the Boston Facility. (*Id.* ¶¶ 71, 269.) A few months later

on the Q1 2020 earnings call, Coleman stated that the Boston Facility was "pretty much running normal capacity and during this period of lower demand, [the Boston Facility is] actually building safety stock." (*Id.* ¶ 299.) Around the same time, at the UBS Global Virtual Healthcare Conference, Anderson reiterated this sentiment, stating that "in terms of the Boston facility, that's the one that really is untouched from an overall manufacturing plan perspective. We're continuing to run that factory as before in order for us to use this time to build up safety stock in SurgiMend and PriMatrix." (*Id.* ¶ 301.) Approximately five months later, on October 28, 2020, on the Q3 2020 earnings call, when asked about supply, Coleman responded "I think about our Boston plant which makes SurgiMend and PriMatrix. And we've actually built more safety stock for those regenerative products. So we're in very good shape." (*Id.* ¶ 303.) On the same call, when addressing the Company's ability to meet demand, Anderson also stated that "high single, low double digit is what we're definitely positioned for within the TT [Tissue Technologies] portfolio." (*Id.*)

On May 20, 2021, during Integra's 2021 Virtual Investor Day, Coleman stated that "'work' remediating the Boston Facility 'is now complete,'" and the work provided the Company with "a manufacturing footprint that's . . . able to produce quality products." (*Id.* ¶ 72.) He stressed that "[t]he key takeaway here is we've strengthened our quality operating mechanisms and reduced quality risk with enhanced rigor and this has led to better FDA inspection results." (*Id.* (emphasis omitted).)

3. 2021 Inspection

In fall of 2021, the FDA inspected the Boston Facility, and it again found violations of the cGMP regulations and issued a Form 483 ("2021 Form 483"). (*Id.* ¶ 118.) The 2021 Form 483 outlined violations in two major areas: (1) environmental control violations; and (2) process

validation controls. (*Id.* ¶¶ 119-21.) During its investigation, the FDA found that Integra had not remedied a number of issues outlined in the 2019 Warning Letter, despite its assurances to the FDA that such CAPAs would have been implemented and remediated by fall of 2021. (*Id.* ¶¶ 119, 121.) In particular, the FDA found that Integra had not implemented CAPAs concerning required "alert and action levels" for the Clean Rooms that Integra assured would be remediated by April 2019. (*Id.* ¶ 119.) The FDA also found that Integra had not implemented a CAPA concerning bacterial endotoxin testing processes despite its assurance in February 2019 that it had already been implemented. (*Id.* ¶ 121.) Moreover, the FDA found repeated data integrity violations, which were also discovered in the 2018 Inspections Reports. (*Id.* ¶ 119.) Integra disclosed the 2021 Form 483 in its 2021 Form 10-K, in February 2022, and stated that the "[2019] Warning Letter and the 2021 Form 483 do not restrict the Company's ability to manufacture or ship products or require the recall of any products."[4] (*Id.* ¶ 123, 305.)

On April 5, 2022, Integra's Senior Vice President of Operations informed the Braintree Town Council's Ways & Means Committee that the Company's Board of Directors had approved relocating the Boston Facility to a new, state-of-the-art facility about twenty minutes south of Boston, in Braintree (the "Braintree Facility"). (*Id.* ¶ 166.) The Company expected that construction of the Braintree Facility would be complete in Q4 2023, "with occupancy at the end of 2024 and full production at the end of 2025 into 2026." (*Id.* ¶ 167.) The CAC alleges that management had thus decided to abandon the Boston Facility as early as spring of 2021, which played a key role in management's decision to forego the remediation required at the Boston Facility. (*Id.* ¶¶ 168-69.) In particular, FE 9—a "Continuous Improvement Specialist"—recounts

[4] Over seven months later, in its 2021 Environmental, Social & Governance ("ESG") Report, Integra touted its mechanisms and processes it used to ensure quality and compliance with regulatory requirements. (*Id.* ¶ 288.)

that a representative from executive management explained the Company's plan to relocate manufacturing at the Boston Facility to the Braintree Facility at a "town-style meeting" during the summer of 2021. (*Id.* ¶ 165.)

4. 2022 Whistleblower Complaint

On October 20, 2022, an Integra employee called the Company's compliance hotline to report issues related to Integra's "inspection process, bacterial endotoxin testing, bovine hide/sin thickness measurements, and control of sterilized devices" (the "2022 Whistleblower Complaint"). (*Id.* ¶ 139.) As a result, Integra began an internal investigation into the Boston Facility. (*Id.* ¶ 140.) Integra's compliance team found thirty-seven adulterated lots and issued a distribution hold on those lots on December 14, 2022, along with a hold on new product production. (*Id.*) In January 2023, Integra expanded the manufacturing hold beyond new products to all work-in-progress products as well. (*Id.* ¶ 141.)

5. 2023 Inspection

The FDA began a for-cause inspection of the Boston Facility in March 2023 as a result of the 2022 Whistleblower Complaint. (*Id.* ¶ 142.) Before receiving the results of this inspection, Integra and the Individual Defendants made additional statements concerning the Boston Facility. (*See id.* ¶¶ 273, 307.) On April 26, 2023, on its Q1 2023 earnings call, De Witte stated that Integra had "been working for the past couple of years to upgrade [its] Boston [F]acility based on FDA observations in 2018 and 2021," and that "[w]e had an audit early in March that confirms we're on the right track with our execution." (*Id.* ¶ 273.) About a week later, at Integra's Analyst/Investor Day, Leonard proclaimed that Integra "made significant investments in quality across all of our manufacturing sites with a focus on accelerating our quality project in Boston involving testing, infrastructure, and physical layout changes." (*Id.* ¶ 290.) He also touted that relocating the Boston

Facility to the Braintree Facility was going to double the capacity for SurgiMend and ProMatrix in 2025. (*Id.* ¶ 273, 307.)

6. 2023 Form 483

On May 17, 2023, the FDA issued another Form 483 ("2023 Form 483") for continuing cGMP violations in three major areas. (*Id.* ¶¶ 144-152.) First, the FDA found seven contamination control and process validation control violations, which included violations originally detected in the 2018 Inspection Reports. (*Id.* ¶ 145.) For example, Integra still "failed to monitor or control potential bacterial endotoxin contamination" and still suffered from data integrity issues. (*Id.* ¶¶ 145-46.) Second, the FDA found product non-conformance control violations, which included repeated incidents of the Company releasing products that exceeded bacterial endotoxin specifications. (*Id.* ¶¶ 148-49.) Third, the FDA found CAPA control violations because Integra failed to implement procedures for corrective and preventative action, despite Integra making assurances since the 2018 Inspection Reports that it had done so. (*Id.* ¶¶ 150-52.) The FDA also found that Integra violated CAPA controls in response to the 2022 Whistleblower Complaint by failing to "investigate the potential health impact" of that complaint. (*Id.* ¶ 152.) Integra replied to the 2023 Form 483 on June 8, 2023, acknowledging the need for additional remediation plans and assuring the FDA that it would complete the remediation activities identified before the 2023 inspection. (*Id.* ¶¶ 154-55.)

In the interim, on April 26, 2023, Integra issued a press release announcing that it had paused production at the Boston Facility since March 2023, (*id.* ¶¶ 170-71), and on May 23, 2023, Integra filed a Form 8-K that announced a "voluntary global recall" of all products manufactured at the Boston Facility between March 1, 2018 and May 22, 2023 (*id.* ¶ 179).

7. 2023 Warning Letter

On July 17, 2023, the FDA sent Integra a warning letter (the "2023 Warning Letter"), addressed to De Witte. (*Id.* ¶ 156.) The 2023 Warning Letter ultimately concluded that the products manufactured at the Boston Facility were "adulterated." (*Id.*) In the 2023 Warning Letter, the FDA expressed concern that it identified many of the same violations identified in the 2019 Warning Letter and that Integra had not yet identified all of the corrective actions necessary. (*Id.*) The 2023 Warning Letter also concluded that despite the voluntary global recall and production pause, Integra's remediation efforts were "not adequate" and going forward it needed to obtain a certification from an outside expert consultant concerning the cGMP requirements and submit that report to the FDA. (*Id.* ¶ 158.) The FDA directed that Integra was to submit the initial outside certification by March 31, 2024 and all subsequent certifications between March 31, 2025 and March 31, 2026. (*Id.* ¶ 159.)

8. Alleged Disclosures

Plaintiff alleges that there were five corrective disclosures to the market. *First*, on April 26, 2023, Integra issued a press release announcing that it had paused production at the Boston Facility in March 2023 "while pulling forward quality system upgrades project [sic] into the first half of 2023," and De Witte also discussed this production freeze for an "8-week focused project" on a conference call. (*Id.* ¶¶ 170-71.) The same day, Integra's stock price fell $4.64 per share, or nearly 8%, to close at $54.20. (*Id.* ¶ 173.)

Second, on May 23, 2023, Integra filed a Form 8-K that announced a "voluntary global recall" of all products manufactured at the Boston Facility between March 1, 2018 and May 22, 2023, and it revised its financial guidance for Q2 2023 downward. (*Id.* ¶¶ 179, 181.) The same day, Integra's stock price fell $10.24 per share, or 22.5%, to close at $40.48. (*Id.* ¶ 182.)

Third, on February 28, 2024, Integra announced in a press release that De Witte was retiring, along with a "leadership transition plan," and it announced disappointing financial results for Q4 2023 and guidance for 2024, which was in part due to issues at the Boston Facility. (*Id.* ¶¶ 196-97.) De Witte also held a conference call that day to discuss Integra's financial performance and forecasts. (*Id.* ¶ 198.) The same day, Integra's stock price fell $5.60 per share, or 13.5%, to close at $38.67. (*Id.* ¶ 200.)

Fourth, on May 6, 2024, Integra issued a press release and held an earnings call announcing that the external audit of the Boston Facility resulted in "more findings than [Integra] anticipated," and that it would not be able to resume commercial distribution in 2024. (*Id.* ¶¶ 202-03.) Integra removed the SurgiMend and PriMatrix devices completely from its 2024 guidance, which lowered its projected financial results. (*Id.* ¶ 203.) The same day, Integra's stock price fell $5.75 per share, or 22.5%, to close at $23.14. (*Id.* ¶ 208.)

Fifth and finally, on July 29, 2024, Integra filed a Form 8-K and held an earnings call where it announced the "compliance master plan," shipping holds, and its plans to permanently close the Boston Facility and move those operations to Braintree, which would not be operational until 2026. (*Id.* ¶¶ 214-17.) The same day, Integra's stock price fell $6.01 per share, or 21%, to close at $25.42. (*Id.* ¶ 222.)

9. Integra's Alleged Awareness of cGMP Deficiencies and Lack of Remediation

The CAC alleges that contrary to the assurances Integra made publicly after the 2019 Warning Letter, it did not undertake substantial remediation efforts and strengthen the operating mechanisms at the Boston Facility, but rather it implemented "a million Band Aids." (*Id.* ¶ 95.) For example, FE 1, Integra's former Chief Scientific Officer from February 2014 to October 2021, describes how the age and layout of the Boston Facility provided serious obstacles to remediation,

which was discussed in monthly meetings with senior management and executive leadership, including Arduini, Coleman, and Anderson. (*Id.* ¶¶ 94, 96.)

In sum, Lead Plaintiff alleges that from 2019 through 2024, the FDA repeatedly warned Defendants of deficient manufacturing conditions, including the failure to monitor or control potential bacterial endotoxin contamination and to implement CAPAs. Lead Plaintiff avers that despite repeated warnings, Defendants failed to take sufficient remediation action necessary to address these deficiencies. Through fifteen confidential witnesses, the CAC alleges that despite Defendants' failure to take such action, they nonetheless touted their remediation efforts, as well as the quality and quantity of product being manufactured at the Boston Facility. The CAC alleges that the following twenty-eight statements made by the Company or an Individual Defendant are false or misleading statements of material fact:[5]

- Statement 1: On March 11, 2019, Integra filed a Form 8-K, which stated that "since the conclusion of the [FDA] inspection, [Integra] has undertaken significant efforts to remediate the observations and continues to do so." (CAC ¶ 267 (emphasis omitted).)

- Statement 2: On March 11, 2019, Integra filed a Form 8-K, which stated that the 2019 Warning Letter "does not restrict the Company's ability to manufacture or ship products or require the recall of any products." (*Id.* ¶ 295 (emphasis omitted).)

- Statement 3: On February 19, 2020, during Integra's Q4 2019 earnings call, "Anderson stated that the Company had experienced 'supply constraints' due to temporary measures that caused 'limited production' at the Boston Facility. In response to an analyst question for more detail on these changes at the Boston Facility, Defendant Coleman assured investors: 'You probably remember we went through an FDA audit. We've been doing quality remediation efforts throughout 2019. There are no patient safety issues here [at the Boston Facility].'" (*Id.* ¶ 269 (emphasis omitted).)

[5] The Court follows the numbering convention in Exhibit 1 of Defendants' moving brief. The Court notes that Plaintiff also followed the same convention in its opposition brief. (*See generally* Defs.' Moving Br., Ex. 1, ECF No. 68-3; Pl.'s Opp'n Br., ECF No. 72.)

- Statement 4: On February 19, 2020, during Integra's Q4 2019 earnings call, Coleman stated that the Company had made "changes . . . to the actual physical [Boston] [F]acility" after the Company "went through an FDA audit" specifically designed to "get [the Company] 50% more capacity as [it] enter[s] 2020." (*Id.* ¶ 297 (emphasis omitted).)

- Statement 5: On May 7, 2020, during Integra's Q1 2020 earnings call, in response to an analyst's question about the Company's "ability to ramp up and compete in the second half of the year and in 2021," Coleman stated that the Boston Facility was "pretty much running normal capacity and during this period of lower demand, we're actually building safety stock." He added that the Company's regenerative tissue products like SurgiMend, "should see very good growth when things come back to normal or we get back to the regular procedure," which would be "double-digit growth," and further assured investors that the Company would "have plenty of safety stock to support that ramp when it comes to back." (*Id.* ¶ 299 (emphasis omitted).)

- Statement 6: On May 20, 2020, Anderson attended the UBS Global Virtual Healthcare Conference on behalf of Integra. An analyst, noting that Integra's "wound care" product line was "an important franchise for the company," requested an update on "the factors driving the wound business" and "what's going on in the manufacturing side." Anderson responded that "in terms of the Boston facility, that's the one that really is untouched from an overall manufacturing plan perspective. We're continuing to run that factory as before in order for us to use this time to build up safety stock in SurgiMend and PriMatrix." (*Id.* ¶ 301 (emphasis omitted).)

- Statement 7: On October 28, 2020, during Integra's Q3 2020 earnings call, Anderson stated, in response to an analyst's question about the Company's "Tissue Technologies' segment" and the Company's "ability to meet demand" that "high single, low double digit is what we're definitely positioned for within the TT [Tissue Technologies] portfolio." (*Id.* ¶ 303 (emphasis omitted).)

- Statement 8: On October 28, 2020, during Integra's Q3 2020 earnings call, Anderson directed Coleman to "talk a little bit about supply." Coleman responded, "we're in great shape when you look at our regenerative supply." He added, "I think about our Boston plant which makes SurgiMend and PriMatrix. And we've actually built more safety stock for those regenerative products. So we're in very good shape." (*Id.* (emphasis omitted).)

- Statement 9: On May 20, 2021, during Integra's 2021 Virtual Investor Day conference, Coleman stated that Integra "made investments in [its] core plants," including the Boston Facility, and told investors that Integra's "work is now complete" and that these investments equipped Integra with "a manufacturing footprint that's . . . able to produce quality products and staffed with colleagues with deep expertise in manufacturing complex products." (*Id.* ¶ 271 (emphasis omitted).)

- Statement 10: On May 20, 2021, during Integra's 2021 Virtual Investor Day conference, Coleman also stated: "The key takeaway here is we've strengthened our quality operating mechanisms and reduced quality risk with enhanced rigor and this has led to better FDA inspection results." (*Id.* (emphasis omitted).)

- Statement 11: On February 24, 2022, Integra filed its Form 10-K for FY 2021, which stated that the "[2019] Warning Letter and the 2021 Form 483 do not restrict the Company's ability to manufacture or ship products or require the recall of any products."[6] (*Id.* ¶ 305 (emphasis omitted).)

- Statement 12: On September 30, 2022, Integra issued its 2021 ESG Report in which the Company stated that it had "numerous mechanisms and processes embedded within our business operations to protect and ensure product quality, continuously improve the effectiveness of our quality management system, and ensure compliance with all regulatory requirements." (*Id.* ¶ 288 (emphasis omitted).)

- Statement 13: On September 30, 2022, Integra issued its 2021 ESG Report in which the Company stated that: "To avoid defects and deliver the highest quality products, Integra adheres to Good Manufacturing Practices (GMPs), Quality System Regulations (QSRs), Good Laboratory Practices (GLPs), Good Tissue Practices (GTPs) and guidelines for conducting clinical studies." (*Id.* (emphasis omitted).)

- Statement 14: On April 26, 2023, during Integra's Q1 2023 earnings call, De Witte stated, "we've been working for the past couple of years to upgrade our Boston [F]acility based on FDA observations in 2018 and 2021." He also stated "as we are preparing to have SurgiMend PMA product there, the Boston site requires a quality system that operates at a higher level. So that's . . . a project that's been ongoing. We had an audit early in March that confirms we're on the right track with our execution." (*Id.* ¶ 273 (emphasis omitted).)

- Statement 15: On May 4, 2023, at Integra's Analyst/Investor Day, Leonard stated, "the relocation of our Boston [F]acility to a new PMA-ready site in nearby Braintree will more than double our capacity for SurgiMend and PriMatrix in 2025." (*Id.* ¶ 307 (emphasis omitted).)

- Statement 16: On May 4, 2023, at Integra's Analyst/Investor Day, Leonard stated, "[l]ast year and this year, we made significant investments in quality across all of our manufacturing sites with a focus on accelerating our quality project in Boston involving testing, infrastructure, and physical layout

[6] The FY 2021 Form 10K was signed by DeWitte, Anderson, and Mosebrook, and it contained certifications by DeWitte and Anderson as to accuracy and completeness. (CAC ¶ 305.)

changes," and that Integra was "on a path to reach world-class quality assurance across all manufacturing sites." (*Id.* ¶ 290 (emphasis omitted).)

- Statement 17: On July 27, 2023, during Integra's Q2 2023 earnings call, De Witte stated, "we have no specific indications of any product complaints related to high endotoxin levels. Patient safety is non-negotiable for us." (*Id.* ¶ 275 (emphasis omitted).)

- Statement 18: On July 27, 2023, during Integra's Q2 2023 earnings call, De Witte also stated that Integra expects "to resume manufacturing by the end of the fourth quarter of this year [2023]" and "to initiate a commercial relaunch by the mid to late second quarter 2024." (*Id.* (emphasis omitted).)

- Statement 19: On July 27, 2023, during Integra's Q2 2023 earnings call, De Witte also stated, "I want to assure our customers and investors that we are highly focused on our remediation efforts, and we fully expect to complete the remediation and return these critical technologies to the market for our customers and their patients." (*Id.* (emphasis omitted).)

- Statement 20: On August 17, 2023, Integra issued its 2022 ESG Report in which Integra stated: "To avoid defects and deliver the highest quality products, Integra adheres to good manufacturing practices (GMPs), quality system regulations (QSRs), good laboratory practices (GLPs), good tissue practices (GTPs) and guidelines for conducting clinical studies." (*Id.* ¶ 292 (emphasis omitted).)

- Statement 21: On August 17, 2023, Integra issued its 2022 ESG Report in which Integra also stated that "product safety and quality are paramount," and that the Company "continuously improves our Quality Management System (QMS) to meet the highest and most current quality standards." (*Id.* (emphasis omitted).)

- Statement 22: On September 6, 2023, at the Wells Fargo Securities Healthcare Conference 2023, Knight stated, in response to an analyst's question about the "production pause and recall" that the "Boston remediation continues to progress well." (*Id.* ¶ 278 (emphasis omitted).)

- Statement 23: On September 6, 2023, at the Wells Fargo Securities Healthcare Conference 2023, Knight also stated that Integra "hired in the right technical expertise to support and drive building a remediation plan and executing against it . . . we are absolutely on the right path, that our timelines to get back into market are real." She said that Integra expected to "begin manufacturing again in the end of this year and that commercial distribution would resume somewhere in the mid to late Q2 2024 timeline." She further stated that the Company underwent "independent reviews . . . to let us know whether or not we were on pace," and "that first independent review and the observations coming out of it say we're still on track for that timeline." (*Id.* (emphasis omitted).)

- Statement 24: On October 25, 2023, during Integra's Q2 2023 earnings call, De Witte stated, "our progress in addressing the Boston [F]acility and returning to the market remains on track. Interim external reviews confirm the adequacy of our remediation plan and the changes made so far and they reflect significant steps made towards the resumption of manufacturing by the end of the fourth quarter 2023 and commercial distribution in mid- to late second quarter '24." (*Id.* ¶ 281 (emphasis omitted).)

- Statement 25: On October 25, 2023, during Integra's Q2 2023 earnings call, De Witte also stated, "we are on track with our communicated timelines." (*Id.* (emphasis omitted).)

- Statement 26: On February 28, 2024, Integra released a report of its Q4 2023 earnings results, which stated that "[r]elaunch remains on track for mid-to-late Q2 2024." (*Id.* ¶ 284 (emphasis omitted).)

- Statement 27: On February 28, 2024, during Integra's Q4 2023 earnings call, De Witte stated that the Boston Facility underwent a "successful dress rehearsal" of the external audit that the Company needed to pass to resume distribution. When asked for "more color" about the dress rehearsal and "why that gives you confidence on the resumption of sales starting in the second quarter," De Witte responded that the dress rehearsal gave the Company "confirmations" and yielded only "limited observations on things that we could have improved." (*Id.* (emphasis omitted).)

- Statement 28: On February 28, 2024, during Integra's Q4 2023 earnings call, De Witte also stated that a "[s]uccessful audit will allow us to start building finished goods inventory to resume distribution mid- to late second quarter." (*Id.* (emphasis omitted).)

D. Procedural History

The original complaint was filed on September 12, 2023 (ECF No. 1), and the CAC was filed on September 6, 2024 (CAC). Plaintiff brings claims alleging violations of Section 10(b) of the Exchange Act and Rule 10b-5 and violations of Section 20(a) of the Exchange Act. (*Id.* ¶¶ 329-52.) On November 12, 2024, Defendants moved to dismiss the CAC in its entirety. (ECF No. 68.) Plaintiff opposed (Pl.'s Opp'n Br.), and Defendants replied (Defs.' Reply Br., ECF No. 74). This motion is now ripe for review.

II. LEGAL STANDARD

A district court must conduct a three-part analysis when considering a motion to dismiss pursuant to Federal Rule of Civil Procedure[7] 12(b)(6). *See Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). The Court must take note of the elements a plaintiff must plead to state a claim; review the complaint to strike conclusory allegations; and accept as true all of the plaintiff's well-pled factual allegations while "constru[ing] the complaint in the light most favorable to the plaintiff." *Id.*; *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (citation omitted). The Court "must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Fowler*, 578 F.3d at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). A facially plausible claim "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 210 (quoting *Iqbal*, 556 U.S. at 678).

A. Section 10(b) Claims

Section 10(b) of the Exchange Act makes it "unlawful for any person . . . [t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe . . . ." 15 U.S.C. § 78j(b). The SEC implemented this prohibition by declaring it "unlawful for any person . . . [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading . . . ." 17 C.F.R. § 240.10b-5(b) ("Rule l0b-5"). The Supreme Court has implied a private right of action from the text and purpose of Section 10(b). *Tellabs, Inc. v. Makor Issues & Rts, Ltd.*, 551 U.S. 308, 318

[7] All references to "Rule" or "Rules" hereafter refer to the Federal Rules of Civil Procedure.

(2007) ("[T]his Court has implied from the statute's text and purpose . . . a right of action to purchasers or sellers of securities injured by its violation.").

To survive a motion to dismiss, a plaintiff bringing an action under Section 10(b) and Rule 10b-5 must plead: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37-38 (2011) (quoting *Stoneridge Inv. Partners, LLC v. Sci.–Atl., Inc.*, 552 U.S. 148, 157 (2008)).

B. Pleading Standards

The Private Securities Litigation Reform Act ("PSLRA") requires plaintiffs bringing Section 10(b) claims "to allege facts giving rise to a 'strong inference' of scienter, which 'must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.'" *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 176 (3d Cir. 2014) (quoting *Tellabs*, 551 U.S. at 314). This heightened pleading standard alters the Court's analytical approach when considering a Rule 12(b)(6) motion to dismiss. *See Tellabs*, 551 U.S. at 322-24. The first step—"accept[ing] all factual allegations in the complaint as true"—is unchanged from the normal analysis. *Id.* at 322. Next, the Court "must consider the complaint in its entirety" and the usual sources and documents the Court would normally consider. *Id.* At this step, "[t]he inquiry . . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id.* at 322-23 (emphasis in original) (citation omitted). At the third step, the Court must "determin[e] whether the pleaded facts give rise to a 'strong' inference of scienter," and "take into account plausible opposing inferences." *Id.* at 323.

"The strength of an inference cannot be decided in a vacuum." *Id.* Instead, "[t]he inquiry is inherently comparative." *Id.* The Court "must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Id.* at 324. While the inference "need not be irrefutable, i.e., of the 'smoking-gun' genre, . . . the inference of scienter must be more than merely 'reasonable' or 'permissible'—it must be cogent and compelling, thus[,] strong in light of other explanations." *Id.* (citations omitted).

C. Section 20(a) Claims

To survive a motion to dismiss, a plaintiff bringing an action under Section 20(a) must plead: "(1) an underlying primary violation by a controlled person or entity; (2) that [the defendants] exercised control over the primary violator; and (3) that the [d]efendants, as 'controlling persons,' were in some meaningful sense culpable participants in the fraud." *Wilson v. Bernstock*, 195 F. Supp. 2d 619, 642 (D.N.J. 2002). "Liability under Section 20(a) is predicated upon an independent violation of [the Exchange Act] or the rules or regulations thereunder." *Id.* (internal quotation marks omitted) (quoting *In re Party City Sec. Litig.*, 147 F. Supp. 2d 282, 317 (D.N.J. 2001)).

III. DISCUSSION

Defendants move pursuant to Rules 9(b), 12(b)(6), and the PSLRA, arguing that Plaintiff fails to plead essential elements of each claim. (*See generally* Defs.' Moving Br., ECF No. 68-1.) Defendants argue that the CAC fails to plead: (1) "with particularity a false or misleading statement about cGMP compliance, remediation of quality systems, or production capacity because the statements are inactionable puffery, opinion, forward-looking, and/or not shown to be false when made"; (2) a strong inference of scienter; (3) loss causation after May 23, 2023;

(4) "scheme liability through manipulative conduct or deceptive acts"; and (5) specific facts as to each Individual Defendant. (*Id.* at 2-3.)

A. Defendants' Exhibits

As an initial matter, the Court must address the forty-two exhibits attached to Defendants' motion, which consist of FDA documents, SEC filings, call and presentation transcripts, news articles, ESG reports, a recall notice, and a press release. (*See* Exs. 1-43, ECF No. 68.) Plaintiff argues that Defendants' request for the Court to take judicial notice of the forty-two exhibits "is improper without formal motion for the Court and parties' consideration." (Pl.'s Opp'n Br. 15 n.3.) Defendants argue in reply that no formal motion is necessary, and that courts consistently consider such documents in motions to dismiss securities actions without formal notice. (Defs.' Reply Br. 1 n.1.)

When deciding a motion to dismiss, the Court "generally consider[s] only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (quoting *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993)). An exception to this general rule is that the Court may consider "a document integral to or explicitly relied upon in the complaint," without converting the motion to dismiss into a motion for summary judgment. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (emphasis in original) (citation omitted). The critical question is "whether the claims in the complaint are 'based' on an extrinsic document and not merely whether the extrinsic document was explicitly cited." *Schmidt*, 770 F.3d at 249 (citation omitted).

The Court may also consider "items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case." *Buck v. Hampton Twp. Sch. Dist.*, 452

F.3d 256, 260 (3d Cir. 2006) (citation omitted). Federal Rule of Evidence 201(b)(2) provides: "The [C]ourt may judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Items such as SEC filings "are matters of public record of which the [C]ourt can take judicial notice." *Schmidt*, 770 F.3d at 249.

First, the Court agrees with Defendants that no formal motion is required for the Court to judicially notice certain documents. *See* Fed. R. Evid. 201(c), (e), Advisory Committee's Notes ("No formal scheme of giving notice is provided."). Here, the Court takes judicial notice of Exhibits 2, 3, 5, 7-9, 11-12, 15, 18, 20-22, 25-28, 30, 33-35, and 37 because they are integral to or relied upon in the CAC. (*See generally* CAC.) Indeed, most of these documents are quoted in the CAC. The Court also takes judicial notice of Exhibits 4, 6, 10, 16-17, 19, 23-24, 29, 31-32, and 36 because they are SEC filings, the accuracy of which cannot reasonably be questioned. *See Schmidt*, 770 F.3d at 249. Because Exhibits 38-43 are all documents created by the FDA, the Court will judicially notice those exhibits "as authentic public reports or other documents prepared by an administrative agency pursuant to government regulation." *In re Plum Baby Food Litig.*, 637 F. Supp. 3d 210, 220 (D.N.J. 2022) (judicially recognizing FDA documents found on the FDA's website); *see also In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) (taking judicial notice of a published report on the FDA's website). The Court will also take judicial notice of Exhibits 13 and 14, which are news articles, because a court may take judicial notice of news articles at the motion to dismiss stage. *Turnofsky v. electroCore, Inc.*, No. 19-18400, 2021 WL 3579057, at *3 (D.N.J. Aug. 13, 2021). The Court, however, only takes notice that these articles were "in the public realm at the time" and not whether their contents are in fact true. *Benak ex rel. All. Premier Growth Fund v. All. Cap. Mgmt. L.P.*, 435 F.3d 396, 401 n.15 (3d

Cir. 2006). The Court, therefore, will take judicial notice of all of the exhibits attached to Defendants' moving brief for the reasons articulated above.

B. Section 10(b) of the Exchange Act and Rule 10b-5

1. Scienter

Scienter is "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319 (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976)). To allege scienter, a plaintiff must plead "with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *In re Elecs. for Imaging, Inc. Sec. Litig.*, No. 17-5992, 2019 WL 397981, at *6 (D.N.J. Jan. 31, 2019) (quoting 15 U.S.C. § 78u-4(b)(2)(A)). While a plaintiff does not need to present the court with a "smoking-gun," *In re Hertz Glob. Holdings, Inc.*, 905 F.3d 106, 114-15 (3d Cir. 2018), a "strong" inference is not merely reasonable or permissible—it must be "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Fain v. USA Techs., Inc.*, 707 F. App'x 91, 95 (3d Cir. 2017) (quoting *Tellabs*, 551 U.S. at 324).

Scienter can be established through knowledge or recklessness. *Fain*, 707 F. App'x at 95-96. "[C]ourts must analyze the complaint holistically to determine whether its allegations, 'taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.'" *In re Hertz*, 905 F.3d at 114; *Tellabs*, 551 U.S. at 323 (noting that the inquiry is "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter"). The relevant inquiry for recklessness is whether defendants "should have known that they were misrepresenting material facts related to the corporation[,]" i.e., when defendants had "knowledge of facts or access to information contradicting their public

statements." *In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 599 (D.N.J. 2001) (quoting *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000)).

The CAC alleges scienter through a number of different categories of statements: (1) the FDA's inspections and issuance of Forms 483, EIRs, and Warning Letters (CAC ¶¶ 225-33); (2) the 2022 Whistleblower Complaint (*id.* ¶¶ 234-35); (3) confidential statements from former employees ("FE") (*id.* ¶¶ 236-48); (4) relocation of the Braintree Facility (*id.* ¶¶ 249-55); (5) the importance of regulatory compliance to Integra's business (*id.* ¶¶ 256-58) and the importance of SurgiMend and PriMatrix to Integra (*id.* ¶ 264); and (6) Defendants' assurances that management was focused on Boston Facility remediation (*id.* ¶¶ 259-63). The Court addresses each in turn.

a. FDA's Inspections and Issuance of Forms 483, EIRs, and Warning Letters

Plaintiff alleges that the FDA's inspections and issuance of Forms 483, EIRs, and Warning Letters are evidence of scienter because they put each Defendant on notice of the cGMP violations and that Integra was manufacturing the SurgiMend and PriMatrix in conditions prone to endotoxin contamination. (CAC ¶¶ 225, 233.) Defendants argue that this allegation fails because a finding of scienter requires sufficient allegations that Defendants knew or recklessly disregarded undisclosed facts, and Integra promptly disclosed the FDA's regulatory correspondence. (Defs.' Moving Br. 25-26.) Plaintiff argues in opposition that these FDA notices show that Defendants knew that the Boston Facility had cGMP violations, and they were required to fix them, yet they failed to do so while assuring investors they were remediating the violations. (Pl.'s Opp'n Br. 32-33.)

The Court finds that Defendants' knowledge of the FDA inspections and resulting correspondence do not support an inference of scienter. As Defendants note, Integra disclosed the 2018 Inspection Reports (Defs.' Moving Br., Ex. 3 at 2, ECF No. 68-5), 2019 Warning Letter (CAC ¶ 64), 2021 Form 483 (*id.* ¶ 123), 2023 Form 483 (Defs.' Moving Br., Ex. 24 at 4-5, ECF

No. 68-26), and 2023 Warning Letter to investors (*id.*). Such disclosure of correspondence with the FDA "undercut any inference of scienter." *Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc.*, 778 F.3d 228, 244 (1st Cir. 2015).

b. 2022 Whistleblower Complaint

Plaintiff alleges that the 2022 Whistleblower Complaint put each Defendant on notice that the Boston Facility was in violation of the cGMPs and "supports an inference of severe recklessness at a minimum." (CAC ¶¶ 234-35.) Defendants argue that the 2022 Whistleblower Complaint does not support an inference of scienter before the date it was made on October 20, 2022, or after April 26, 2023, the date on which Integra disclosed the impact of the 2022 Whistleblower Complaint. (Defs.' Moving Br. 26-27.) As far as the period between October 20, 2022 and April 26, 2023, Defendants argue that the 2022 Whistleblower Complaint cannot show scienter because Plaintiff does not challenge any statements during that time period. (*Id.* at 27.) Plaintiff argues in opposition that the 2022 Whistleblower Complaint put Defendants on notice, which can strengthen the inference of scienter. (Pl.'s Opp'n Br. 35-36.) The Court disagrees with Plaintiff.

The single case that Plaintiff cites to support its argument is inapposite. In *Twin Master Fund, Ltd. v. Akorn, Inc.*, the court found that plaintiff adequately pled scienter where the defendant did not disclose an employee complaint at all. No. 19-3648, 2020 WL 564222, at *14 (N.D. Ill. Feb. 5, 2020). Here, while Defendants did not disclose the 2022 Whistleblower Complaint immediately upon receipt, they did launch an internal investigation (CAC ¶ 234), and "the launching of an investigation is not sufficient to suggest scienter." *Christian v. BT Grp. PLC*, No. 17-497, 2020 WL 1969941, at *6 (D.N.J. Apr. 24, 2020), *aff'd sub nom., Pamcah-UA Loc. 675 Pension Fund v. BT Grp. PLC*, No. 20-2106, 2021 WL 3415060 (3d Cir. Aug. 5, 2021). In fact, courts have found that "an internal investigation tends to undermine any inference of

scienter." *Salim v. Mobile Telesystems PJSC*, No. 19-1589, 2021 WL 796088, at *14 (E.D.N.Y. Mar. 1, 2021), *aff'd*, No. 21-839, 2022 WL 966903 (2d Cir. Mar. 31, 2022). The Court, therefore, finds that the 2022 Whistleblower Complaint does not support an inference of scienter.

Moreover, even if the 2022 Whistleblower Complaint did generally support an inference of scienter, the Court agrees with Defendants that it could not have any bearing on scienter for Statements One through Thirteen, which were made before the whistleblower called in the complaint. *See In re Telefonaktiebolaget LM Ericsson Sec. Litig.*, 675 F. Supp. 3d 273, 299 (E.D.N.Y. 2023), *aff'd sub nom., Bos. Ret. Sys. v. Telefonaktiebolaget LM Ericsson*, No. 23-940, 2024 WL 4023842 (2d Cir. Sept. 3, 2024) (finding that "the 2019 internal investigation plainly can have no bearing on scienter for the MEA Business Statements and Policy Statements, which were made in 2017 and 2018"). And Defendants correctly note that there were no allegedly false or misleading statements made between October 20, 2022 and April 26, 2023, and therefore the 2022 Whistleblower Complaint does not support scienter during that time period. (*See* CAC ¶¶ 265-308.) After April 26, 2023, Integra disclosed the impact of the 2022 Whistleblower Complaint—the production pause at the Boston Facility—further undercutting any inference of scienter. (*Id.* ¶¶ 170, 234.)

c. Confidential FE Statements

Plaintiff puts forward various allegations concerning scienter related to the Boston Facility's remediation based on information sourced to fifteen unnamed confidential former employees ("FE"). (*See generally* CAC.) The Court considers these allegations below.

In general, "confidential witnesses start out a step behind as to particularity," and "[t]o close the gap, the federal courts have required additional information from confidential witnesses." *Wu v. GSX Techedu Inc.*, 738 F. Supp. 3d 527, 542 (D.N.J. 2024). To determine the weight that should be given to confidential sources in a complaint, a court must evaluate the "detail provided

by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia." *Avaya*, 564 F.3d at 263 (quoting *Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 147 (3d Cir. 2004)). If, after that assessment, "anonymous source allegations are found wanting with respect to these criteria . . . [courts] must discount them steeply." *Id.*

Here, the Court finds—when considered collectively—that the allegations of the FEs do not adequately plead a strong inference of scienter as required under the PSLRA. *Tellabs*, 551 U.S. at 323. As analyzed in further detail below, Defendants clearly knew about the cGMP violations throughout the Class Period, but the FE statements do not plead with adequate detail facts that allow the Court to infer intent. It is not enough for Defendants to know about the violations—they must have acted with the "intent to deceive, manipulate, or defraud" at the time that the allegedly false or misleading statements were made *Id.* at 319. The Court evaluates each FE below.

i. FE 1

FE 1 was Integra's Chief Scientific Officer from February 2014 through October 2021. (CAC ¶ 94.) As Chief Scientific Officer, FE 1 "often worked with the Quality Assurance department for the Boston Facility . . . , including when adverse events occurred at the plant." (*Id.* at ¶ 94 n.5.) FE 1 explained that "the Boston Facility's age and layout presented obstacles to remediation that were discussed at the highest levels of the Company." (*Id.*) He further explained that the Boston Facility was a "four-story warehouse on the south side of Boston that was between 50 to 100-years-old" and compared it to 'buying an old farmhouse that has lead pipes, and you have to change all piping, all the walls and rebuild it,' fixing all the issues becomes a 'money pit.'" (*Id.*) As a result, he notes that it would have taken years and been costly to install the proper water

handling and air handling systems, and therefore Integra was "forced to implement 'a million Band Aids.'" (*Id.* ¶ 95.) He confirmed that these issues "were discussed with Integra's senior management and executive leadership, including Defendants Arduini, Coleman and Anderson, during monthly review meetings, in which Integra's quality and regulatory teams led presentations on the operations of each facility, including the Boston Facility." (*Id.* ¶ 96.) He further states that "[d]uring these meetings, members from the quality and regulatory teams presented on each Integra facility, whether they had any adverse events, and the status of any FDA inspections, and progress of any remedial work." (*Id.*) The Complaint alleges:

> [FE 1] explained that, "whether it was remodeling, production, or supplies, there was no month that Boston was [s]cotfree." FE 1 recounted that the Company extensively discussed proposals to move production away from the Boston Facility because "it was an old facility where they were always fixing something, and they needed to tear it down and build it up." However, the Company decided against pursuing these proposals because of the disruption they would have caused to the Company's manufacturing.

(*Id.* ¶ 97.) Here, the Court finds that FE 1 provides sufficient detail about his role and time in the role, along with his basis of knowledge on the C-suite and as a member at management meetings. As such, "the factors used to evaluate the overall reliability of information from confidential sources do not reveal a basis to steeply discount the information," and the Court will therefore take the information from FE 1 as true. *City of Warren Police & Fire Ret. Sys. v. Prudential Fin., Inc.*, 70 F.4th 668, 693 (3d Cir. 2023).

The Court, however, is not convinced that FE 1 alleges facts sufficient to plead a strong inference of scienter. While he explains that remediation at the Boston Facility would have been costly and time-consuming (*id.* ¶¶ 94-95), and that senior management, including Arduini, Coleman and Anderson, discussed such issues at least monthly at meetings (*id.* ¶¶ 96-97), he does not allege facts that suggest that those defendants had the "intent to deceive, manipulate, or

defraud." *Tellabs*, 551 U.S. at 319. Rather, this shows that Defendants were aware of the issues at the Boston Facility and continually discussed how to address them, given the unique challenges presented by the Boston Facility. Importantly, the Boston Facility cGMP violations had already been disclosed (*see* CAC ¶ 64), and FE 1 does not allege specific information discussed at those meetings that would make Defendants' public statements misleading. The Court, therefore, while giving full credit to FE 1's allegations, does not find them to be indicative of an intent to deceive. *See Abiomed*, 778 F.3d 228 ("[E]ven if the CWs' statements plausibly suggest that [defendant] was acting improperly, they do not show that defendants' statements about company policy and the FDA's inquiries were made with conscious intent to defraud or recklessly.").

ii. FE 2

FE 2 was Integra's Vice President, Head of Strategic Initiatives & Business Development from October 2014 until January 2019. (CAC ¶ 98.) Similar to FE 1, FE 2 described that the Boston Facility was in an old building with old machines and that Integra's executive management, including Arduini, Coleman, and Davis "held monthly management meetings where the Boston Facility's manufacturing operations, including remediation needs and related costs, were regularly discussed." (*Id.*) He also stated that the Company explored transferring manufacturing operations but did not carry out that idea until years later because of the disruption it would have to the manufacturing process. (*Id.*)

As an initial matter, FE 2 left Integra before the Class Period began. (CAC ¶ 1 (defining the Class Period as between March 11, 2019 and July 28, 2024, inclusive). The Court recognizes, however, that "both post-class-period data and pre-class data could be used to 'confirm what a defendant should have known during the class period.'" *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 272 (3d Cir. 2005). As such, the Court finds that FE 2 provides sufficient detail about

his role and time in the role to provide the basis for his knowledge. While the CAC does not explicitly state that FE 2 attended the "management meetings," at this stage the Court will infer in Plaintiff's favor that FE 2 as the Head of Strategic Initiatives & Business Development did attend such meetings. The Court, therefore, fully credits FE 2's allegations and considers them to be true. But even taken as true, these allegations suffer from the same infirmities as FE 1's allegations, as they are not indicative of Defendants' intent to deceive, but rather management discussing its various options for the Boston Facility. *See Abiomed*, 778 F.3d 228.

iii. FEs 3 and 4

FE 3 was Integra's National Director Integrated Delivery Networks East from 2014 until February 2023 and was responsible for executive-level contracting and strategic planning across a number of products. (CAC ¶¶ 99, 99 n.7.) He explained that management knew about the issues at the Boston Facility and about the improvements that could have been made before the FDA ordered the production pause. (*Id.* ¶ 99.) Similar to FE 1 and FE 2, he alleges the monthly meetings with management—which he attended—discussed these issues, stating "there is zero way that the C-Suite was not aware of these issues." (*Id.* ¶¶ 100-04.)

FE 4 served as a Site Quality Director at Integra from January 2021 until March 2022. (CAC ¶ 105.) He explained that the Company's leadership "closely monitored quality control issues at the Boston Facility" and attended monthly meetings concerning the same. (*Id.*)

The Court finds that the CAC provides sufficient detail about FE 3 and 4's roles and time in the roles, along with their basis of knowledge as members at management meetings. But their allegations also run into the same flaw as FE 1 and FE 2 because mere discussion of the known issues at the Boston Facility—keeping in mind that the 2019 Warning Letter was disclosed at the

start of the Class Period (*id.* ¶ 67)—does not provide evidence of Defendants' alleged state of mind to defraud. *See In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d at 360; *Abiomed*, 778 F.3d 228.

iv. FE 5

FE 5 worked at Integra at the Boston Facility as a Quality Control Analyst from November 2020 to September 2021, and a Quality Assurance Specialist from September 2021 to June 2023, and was responsible for water testing, conductivity testing, and bioburden testing, as well as Clean Room environmental monitoring. (CAC ¶¶ 108, 108 n.9.) He alleges that the Company did not want to "dig deep" into the issues in the Boston Facility and that there were a number of things he wanted to fix but could not because the Company prioritized profits over quality. (*Id.*)

The Court finds that the CAC provides sufficient detail about FE 5's role and time in the role, along with the basis of his knowledge as to the quality issues at the Boston Facility. His allegations do indicate that the Company was not doing everything it could to remediate the cGMP violations that the FDA found, which could weigh in favor of a finding of scienter. But FE 5 did not have any interaction with the Individual Defendants to suggest that any one of them had the requisite scienter. He puts forth general allegations about "the Company" or "corporate" and the CAC also does not allege whether FE 5 communicated his desire to carry out improvements up the chain of command to the Individual Defendants. As such, FE 5's allegations do not allow for a strong inference of scienter. *See In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 360 (D.N.J. 2007) (finding that a "generic observation . . . provide[d] th[e] [c]ourt neither with facts nor with even a remote indication that [d]efendants operated with the requisite strong scienter"); *In re Watchguard Sec. Litig.*, No. 05-678, 2006 WL 2927663, at *4 (W.D. Wash. Oct. 12, 2006) (holding that plaintiff's allegations did not create a strong inference of scienter where the confidential witnesses did not "have any information regarding any [d]efendant's role in, or

awareness of, these issues" and did not allege whether a confidential witness "communicated any information up the chain of command").

v. FEs 6-9

FE 6 worked at Integra at the Boston Facility as a Manufacturing Technician from December 2019 until December 2020 and as a Team Leader from December 2020 until December 2022. (CAC ¶ 109.) He confirmed that the cGMPs were not followed at the Boston Facility after the 2019 Warning Letter. (*Id.*)

FE 7 served as a Quality Control Analyst at the Boston Facility from September 2020 until November 2020. (CAC ¶ 110.) He confirmed that the cGMP violations continued into 2020 as to validating testing and data integrity. (*Id.*)

FE 8 worked as Integra's Quality Assurance and Regulatory Affairs Consultant at the Company's Cincinnati facility from March 2020 to December 2021 before taking on the same role at the Boston Facility from December 2021 to May 2022. (CAC ¶ 111.) He was tasked with responding to the 2018 Inspection Reports and noted that the Company did not keep adequate records to respond to the FDA. (*Id.* ¶¶ 111-12.) He also explained that there were issues with the sterilization process for Integra's tissue products and that these problems were "well-known at the executive level" because they were "raised in a meeting at the end of 2021 with directors, senior management, and a member of the Board of Directors." (*Id.* ¶ 137.)

FE 9 served as a Continuous Improvements Specialist in Boston, Massachusetts from July 2021 until May 2023 and reported to the General Manager of the Boston Facility. (CAC ¶ 112 n.13.) He was hired to make changes to remediate the cGMP violations and explained that he was not given staff or help to fulfill his role and recounted the continual noncompliance. (*Id.* ¶¶ 112, 112 n.13.)

Even crediting the above FE 6, 7, 8, and 9's allegations as true, they do not give rise to a strong inference of scienter.[8] They do not allege to have "any direct contact with the Individual Defendants at all, let alone know what information they possessed." *Woolgar v. Kingstone Cos., Inc.*, 477 F. Supp. 3d 193, 220 (S.D.N.Y. 2020) (finding that confidential witness statements did "not establish that any of the [i]ndividual [d]efendants knew or honestly believed their statements to be false"); *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d at 360. While FE 8 does make a few references to "executives" or "management," he does not suggest knowledge on behalf of an Individual Defendant that is contrary to an allegedly false or misleading statement.

vi. FEs 10-12

FE 10 worked as a Buyer at Integra's Mansfield Facility from November 2020 to December 2022. (CAC ¶ 114 n.4.) He reported that the Mansfield Facility manufactured poor quality materials and "based on his discussions with other Integra employees," the Boston Facility was just as bad. (*Id.* ¶ 114.)

FE 11 served as a Microbiologist Technician in Integra's plant in Plainsboro, New Jersey. (CAC ¶ 115.) He alleged that the FDA guidelines were rarely ever followed by his team and explained that these issues were not confined to Plainsboro, but rather traced such issues to the Company's leadership "cutting corners." (*Id.*)

FE 12 was a Sterilization and Microbiology Subject Matter Expert for Integra from August 2020 until April 2022 in the Company's Austin, Texas office. (CAC ¶ 116 n.16.) He confirmed that the Company's quality control processes for manufacturing suffered deficiencies. (*Id.* ¶ 116.)

[8] The Court notes the short amount of time that FE 7 spent at the Company, and additionally finds it appropriate to discount his allegations for that reason. He worked at the Company only when Statements 7 and 8 were made during the Q3 2020 earnings call (CAC ¶ 303), something that he is not alleged to have been involved with at all (*see id.* ¶ 110).

FE 10, 11, and 12 did not work at the Boston Facility, and they are not alleged to have any contact with the Boston Facility or interaction with the Individual Defendants. In short, the Court finds that they do not have personal knowledge concerning remediation at the Boston Facility. *See Chubb*, 394 F.3d at 155 (finding that confidential sources were not described with sufficient particularity to support personal knowledge where the witnesses were employed in local branch offices rather than the relevant site).

vii. FE 13

FE 13 served as Integra's Director of Medical Communications from March 2022 until October 2022. (CAC ¶ 125.) He detailed that there were cGMP violations relating to endotoxin contamination at the Boston Facility and that such violations were well-known to the Individual Defendants. (*See id.* ¶¶ 125-27.) He recounted that remediation efforts were not sufficient and that the Company retaliated against employees who reported issues. (*See id.* ¶ 128.)

The only Statements allegedly made during FE 13's tenure at Integra were in the 2021 ESG Report. (*See* CAC ¶ 288.) As the Court has already discussed, knowledge of the violations themselves does not show an intent to deceive. Integra consistently reported the FDA's correspondence with the Company when violations were found. (*See id.* ¶¶ 64, 123; Defs.' Moving Br., Ex. 3 at 2, 4-5); *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 42 (1st Cir. 2014) ("full and prompt disclosure" of FDA correspondence "further undercut any inference of fraudulent intent on the part of defendants").

viii. FE 14

FE 14 served as the Inventory Control Lead at the Boston Facility from June 2022 to July 2023. (CAC ¶ 131 n.19.) He recounted multiple incidents where Integra did not enforce compliance requirements to continue the pace of its manufacturing operations. (*Id.*) He also noted

that he was "not aware of any training on CAPAs" and he "did not get the sense that [the FDA Warning Letter] was serious and there were no formal meetings or formal training on how they were going to address these issues." (*Id.* ¶ 133.)

FE 14 was only at Integra for one year and was present for Statements 12 through 15. (*See id.* ¶¶ 273, 288, 307.) He was a relatively low-level employee who was not responsible for remediation and does not allege any interaction with any Individual Defendants. *See Chubb Corp.*, 394 F.3d at 148–54 (discounting confidential witnesses where they were low-level, branch office employees working in departments other than the department at issue, and thus lacked personal knowledge concerning the defendant's business in a separate department). As such, the Court finds that FE 14's allegations should be discounted. But even taking them as true, FE 14 alleges cGMP violations at the Company in the year leading up to the 2023 Warning Letter. The fact that such violations occurred were disclosed to the public and ultimately do not speak to the intent of Defendants, even if they do reveal wrongdoing. *See Abiomed*, 778 F.3d 228 (finding that confidential witness statements indicating wrongdoing do not necessarily show intent to deceive).

ix. FE 15

FE 15 served as a Manufacturing Process Engineer for the Boston Facility starting in November 2023. (CAC ¶ 161.) "[H]e was responsible for monitoring a crew that used specialized machines in those areas," and he stated that the remediation on the CAPAs never materialized. (*Id.* ¶¶ 161-62.) Specifically, he discussed the noncompliance of refrigerators in the Clean Room and noted that he did not see any improvement while he was there, and if employees reported any issues they were "labeled a problem." (*Id.* ¶ 163.)

FE 15 began working in November 2023, so he could not have any personal knowledge about Integra's Boston Facility remediation until that time. The only statements made after

November 2023 were Statements 26, 27, and 28 made by De Witte on Integra's Q4 2023 earnings call concerning the relaunch and the dress rehearsal for the external audit. (*See* CAC ¶ 284.) His allegations, therefore "do little to demonstrate that any of the challenged statements were false or misleading at the time they were made." *Woolgar*, 477 F. Supp. 3d at 222. FE 15 was a low-level worker who specialized at the Boston Facility, and the CAC does not contain any allegations that FE 15 interacted with the Individual Defendants at all. *See Chubb Corp.*, 394 F.3d at 149 (discounting information from a confidential witness where "[p]laintiffs cite[d] to low-level, locally sited former employees without alleging how or why such employees would have knowledge"). The Court, therefore, heavily discounts FE 15's allegations.

The Court also finds it significant that Plaintiff did not put forth a motive for the Individual Defendants, which although not necessary, "can be persuasive when conducting a holistic review of the evidence." *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 245 (3d Cir. 2013). As such, the Court finds that the FE statements, when taken together, do not adequately plead scienter. While it is not lost on the Court that Integra committed multiple cGMP violations for years and it is possible that there may have been some reckless conduct, the Court simply cannot take the leap from knowledge to intent based on the statements before it. *See Abiomed*, 778 F.3d 228 ("[E]ven if the CWs' statements plausibly suggest that [defendant] was acting improperly, they do not show that defendants' statements about company policy and the FDA's inquiries were made with conscious intent to defraud or recklessly."). Plaintiff's allegations related to the FEs are simply too general for the Court to discern a strong inference of scienter.

d. Braintree Facility

Plaintiff alleges that Defendants' plans to move the Boston Facility to the Braintree Facility support an inference of scienter because it suggests that Defendants never planned to complete the remediation process at the Boston Facility. (CAC ¶¶ 249-50.) Defendants argue that: (1) the plan

to move to the Braintree Facility is not inconsistent with their public statements; and (2) plans to relocate were not solidified until April 1, 2022, according to the CAC, and Defendants disclosed such plans shortly thereafter. (Defs.' Moving Br. 31.) Plaintiff argues in opposition that plans to relocate were "tantamount to an internal acknowledgement that Integra could not remediate the Boston Facility." (Pl.'s Opp'n Br. 39.)

The Court agrees with Defendants that the Company's plans to open the Braintree Facility could be done in conjunction with the remediation of the Boston Facility. Moreover, the fact that Integra announced its plans to open the Braintree Facility (*see* Defs.' Moving Br., Exs. 13, 14, ECF Nos. 68-15, 68-16) the month after the Board approved of the plan (CAC ¶¶ 166, 254) to do so undercuts an inference of scienter.

e. Importance of Regulatory Compliance and Importance of SurgiMend, and PriMatrix

Plaintiff alleges that the fact that Integra's quality control and cGMP compliance were of significant regulatory scrutiny support an inference that the statements alleged to be false were at least recklessly false when made. (CAC ¶¶ 256-58.) But courts have rejected such a "highly regulated industry" theory where, like here, a plaintiff fails to plead sufficient facts that contradicted the allegedly false or misleading statements. *See Metzler Asset Mgmt. GmbH v. Kingsley*, 928 F.3d 151, 166 (1st Cir. 2019).

Regarding the importance of SurgiMend and Primatrix, Plaintiff alleges that the sheer importance of these products, which Defendants frequently spoke with investors about, supports a finding of scienter. As Defendants note, however, while these were high margin products, Integra had over a dozen manufacturing facilities and the Boston Facility only comprised 6 percent of Integra's consolidated revenue during the Class Period. (*See* Defs.' Moving Br., Ex. 4 at 29, ECF

No. 68-6; *id.* at Ex. 36 at 37, ECF No. 68-38.) As such, the Court finds that Plaintiff overstates the importance of SurgiMend and Primatrix and does not find any inference of scienter appropriate.

f. Assurances Related to Management

Next, Plaintiff alleges that Defendants' assurances to investors demonstrate scienter. (CAC ¶¶ 259-63.) But the Court agrees with Defendants that such an argument blurs the distinction between falsity and scienter, and therefore cannot be used as evidence of scienter. *See Joyce v. Amazon.com, Inc.*, No. 22-617, 2023 WL 8370101, at *13 (W.D. Wash. Dec. 4, 2023) ("[I]f the mere decision to speak on a topic were indicative of scienter, there would be no distinction between the element of scienter and the requirement to plead a false statement.").

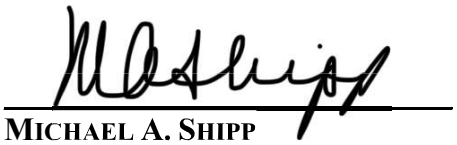
Upon a holistic consideration of the allegations contained in the Amended Complaint, the Court finds that Plaintiff has not adequately pled a strong inference of scienter. Since Plaintiff fails to plead scienter, the Court grants Defendants' motion as to the counts alleging violations under Section 10(b) of the Exchange Act and Rule 10b-5.

C. Section 20(a) of the Exchange Act

To survive a motion to dismiss, a plaintiff bringing an action under Section 20(a) must plead: "(1) an underlying primary violation by a controlled person or entity; (2) that [the defendants] exercised control over the primary violator; and (3) that the [d]efendants, as 'controlling persons' were in some meaningful sense culpable participants in the fraud." *Wilson v. Bernstock*, 195 F. Supp. 2d 619, 642 (D.N.J. 2002). "Liability under Section 20 (a) is predicated upon an independent violation of [the Exchange Act] or the rules or regulations thereunder." *Id.* (internal quotation marks omitted) (quoting *In re Party City Sec. Litig.*, 147 F. Supp. 2d 282, 317 (D.N.J. 2001)). Because Plaintiff's Section 20(a) claim requires a predicate violation of the Exchange Act and because the Court dismisses Plaintiff's Section 10(b) claim, the Court also dismisses Plaintiff's Section 20(a) claim.

IV. CONCLUSION

For the reasons set forth above, Defendants' Motion to Dismiss is granted. The Court will issue an Order consistent with this Memorandum Opinion.



MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE